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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,138	04/12/2004	Kenneth F. Binmoeller	026923-000200US	1173

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EXAMINER

MASHACK, MARK F

ART UNIT	PAPER NUMBER
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3773

MAIL DATE	DELIVERY MODE
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03/17/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/822,138	Applicant(s) BINMOELLER ET AL.	
	Examiner MARK MASHACK	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48,50-53,56 and 58-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48,50-53,56 and 58-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/30/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to a communication dated 11/2/2009. Claims 48 and 50-53, 55, 57-59 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/2/2009 has been entered.

Response to Arguments

2. Applicant's arguments filed 11/2/2009 have been fully considered but they are not persuasive. Applicant argues that **Evard** does not disclose "applying proximal tension to the apparatus to pull the distal anchor proximally against the distal side of the distal tissue layer". Upon further consideration of the prior art and the present invention, Examiner disagrees with this assertion. **Evard** discloses that "the apparatus may be self expanding... such that the radial expansion of the engagement members will occur when surrounding constraint (e.g., constraint of a surrounding catheter wall) has been removed from the apparatus". Examiner asserts that pulling on a constraint catheter as disclosed would inherently pull the distal anchor proximally against the distal side of the

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distal tissue layer while the tension to apparatus is applied, since the catheter is part of the apparatus.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. **Claims 48 and 50-53, 55, 57-58** are rejected under 35 U.S.C. 102(b) as being anticipated by **Evard et al. (“Evard” WO 97/27898)**.

Evard discloses a method of anchoring a tissue to a luminal structure by forming a vascular anastomosis (Page 1, Lines 15-19) comprising the steps of: positioning an apparatus (Page 3, Line 14, - Page 4, Line 8) to a wall of a luminal structure; manually advancing an assembly member **10** comprising a central member **38a, 84, 94** through a tissue penetration; deploying first and second anchors from the central member engaging the tissue on the distal and proximal side **20, 92** wherein the radius of the central member expands (Page 3, Lines 14-22) to provide a lumen (FIG 10) through the tissue. The deploying of the first and second anchors comprises self-expansion (Page 3, Lines 33-37). The anchors comprise a mesh (Page 30, Lines 16-28). **Evard** discloses

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that "the present invention is implanted or installed within openings formed in adjacent blood vessels" (Column 15, Lines 22-32) or "the leading edge of the apparatus may be a sharpened cutting edge or may be otherwise adapted to cut or sever tissue... to form such openings or passageway, or to enlarge, customize, model or otherwise alter the tissue with which it comes into contact" (Column 6, Lines 3-11). Examiner contends that since the apparatus "enlarge[s]" an opening, the apparatus requires that a "pre-formed opening".

5. **Claims 48 and 57-59** are rejected under 35 U.S.C. 102(e) as being anticipated by **Suyker et al. ("Suyker" US 6,966,917)**.

Suyker discloses a method of anchoring proximal and distal tissue layers (Column 1, Lines 20-21) comprising positioning an apparatus next to a wall of the proximal tissue layer; manually advancing the apparatus to penetrate an assembly including a hollow cylindrical central member **3, 4** having a distal and proximal anchors **5, 6**; deploying the distal anchor from the central member such that said distal anchor expands to engage a distal side of the distal tissue layer; applying proximal tension to the apparatus to pull the distal anchor proximally against the distal side of the distal tissue layer while the proximal anchor is deployed and providing a pusher **23** on a proximal side of the assembly to apply a compressive force to expand the radius of the central member (Column 1, Lines 47-64, Column 4, Lines 16-30, and Column 3, Lines 46-51, and Column 7, Lines 23-30).

Conclusion

6. The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Kaster US 5,234,447, Jacob US 5,893,856, Kim US 6,007,544, Allen US 6,113,611, Kanner US 6,348,064, Berg US 6,391,036, Ginn US 6,645,205, Pantages US 6,479,621.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARK MASHACK whose telephone number is (571)270-3861. The examiner can normally be reached on Monday-Thursday 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Mark Mashack/
Examiner, Art Unit 3773

/Melanie Tyson/
Examiner, Art Unit 3773
March 12, 2010